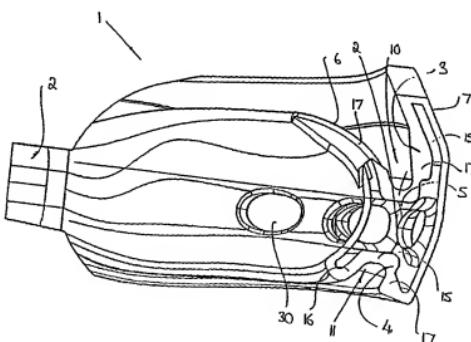




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: ORAL APPLIANCE			



## (57) Abstract

The oral appliance, either a mouthguard or an orthodontic device, includes a base member (2) having a U-shaped form corresponding to a row of teeth of a user. The base member (2) has inner and outer flanges (6, 7) interconnected by a web (5) which collectively define upper and lower channels (10, 11) within which respectively the upper and lower rows of teeth of the user are received. Upper and lower teeth engaging elements (3, 4) are positioned within the upper and lower channels (10, 11). The teeth engaging elements (3, 4) are made of EVA which softens at a temperature of 90-95 °C and are molded to the teeth of the user. The base member (2) remains unaffected by heating to 90-95 °C. The appliance may also include a tongue tag (25) and breathing apertures (30).

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**ORAL APPLIANCE**

This invention relates to an oral appliance.

5 More specifically this invention relates to an oral appliance which is capable of being customised to suit the mouth or oral cavity of a patient or user. This invention also relates to a method of making this appliance using moulding techniques.

10 This invention finds particular but not exclusive application as a mouth guard for use in sports and as an orthodontic appliance for use in correcting myofunctional and tooth alignment problems. It will therefore be convenient to describe the appliance with reference to these example applications. However it is to be clearly understood that the appliance is capable of other applications.

15 While customised orthodontic appliances are known, these are relatively costly. This is because each appliance has to be made individually and separately in a laboratory after a mould or impression of the patient or user's mouth has been obtained. Naturally it would be advantageous if an appliance could be devised

20 which could be mass produced and which was also capable of being adjusted to fit the dimensions of a particular patient's mouth on the spot while the patient was sitting in a dental chair.

Similarly, while customised sports mouthguards are the guards of choice

25 amongst sports people, they are expensive. While mass produced sports mouthguards are known, they have some real limitations. Specifically, because of a wide range of user mouth sizes and shapes, they often do not fit snugly into the mouth of the user. It would also therefore be advantageous if an appliance could be devised which was mass produced and which was also capable of being

customised to fit snugly into a user's mouth.

The applicant has already developed an oral appliance for repositioning the temporomandibular joint. Broadly the appliance comprises a base portion having

5 inner and outer flanges which form respectively upper and lower U-shaped channels for receiving the teeth of upper and lower jaws of a user. The oral appliance is described in detail in the applicant's prior applications PCT/AU90/00399 and PCT/AU92/00592 which are incorporated directly herein by cross reference. The oral appliance correctly positions the temporomandibular

10 joint and positions the lower jaw downwardly and outwardly. This produces advantageous athlete performance as well as a more correct orthodontic positioning of the lower jaw relative to the upper jaw. This encourages an improvement in oral habits and can also provide relief for headaches etc. and other pain conditions. However, the appliance is not capable of being customised

15 to fit a user's mouth. It would therefore be advantageous if a device which had this ability could be innovated.

According to one aspect of this invention there is provided an oral appliance for placing in the mouth of a user, including:

20

a base member having a generally U-shaped form corresponding to the outline of a row of teeth of a user, the base member defining at least one channel within which an upper or lower row of teeth of a user can be received; and

25

a teeth engaging element positioned within each channel, the teeth engaging element being made of a thermoplastic material such that it can be conformed or moulded to suit the individual mouth of a user by heating the element to a temperature at which it is plastic and formable.

In this specification, the term "engaging" shall bear a broad meaning and shall

not be interpreted to mean "retaining" or "latching engagement".

Preferably, the base member has inner and outer flanges interconnected by a web which collectively define upper and lower channels within which respectively the 5 upper and lower rows of teeth are received, and wherein there is an upper said teeth engaging element being received within the upper channel and a lower said teeth engaging element being received within the lower channel.

Thus the upper and lower teeth engaging elements are capable of being moulded 10 to suit the teeth and jaws of a particular user by being heated above their softening point, eg by being immersed in boiling water and then inserted into the mouth of the user. The formable thermoplastic teeth engaging elements can then be conformed to the dimensions and other characteristics of the teeth and jaw of the user. This provides a customised mouth guard or orthodontic positioning 15 appliance without the need for time consuming moulds to be taken of a patient's mouth.

Advantageously each teeth engaging element has a generally U-shaped transverse profile and which is generally U-shaped as a whole to correspond to the outline 20 of a row of teeth of a user.

Preferably, each teeth engaging element is formed of EVA (ethylvinylacetate) which softens at a temperature of 90°C-95°C. EVA has a suitable level of pliability and formability when heated to its softening temperature. 25 Advantageously, the base member is made out of a plastics material which is rigid at temperatures of 90°C-95°C.

While EVA is preferred for the teeth engaging elements, any thermoplastic having a suitable softening temperature may be used. Preferably the element is

malleable at a temperature below 100°C, eg so that it can be softened by immersion in boiling water.

5 The temperature to which the elements must be heated must be reasonable bearing in mind that the appliance is to be placed in the mouth of a patient. It is also important that the thermoplastic does not have any other toxic or other undesirable properties.

10 In a particularly preferred form, each teeth engaging element comprises a layer of thermoplastic material, e.g. EVA, positioned on the base member and having a thickness of 1mm–4mm, preferably 1mm–3mm, e.g. about 2mm.

15 Preferably, a continuous said layer of thermoplastics material forms both the upper and lower teeth engaging elements, said continuous layer also covering a region of the base member intermediate the upper and lower channels, e.g. the outer walls of the flanges.

20 Typically, the continuous said layer of thermoplastic material covers substantially the entire surface area of the base member and the layer is permanently attached to the base member at the time of manufacture. This assists in mounting the layer on the base members which it does by receiving the base member within the layer of thermoplastic material. It is difficult to get EVA to bond to a plastic and this arrangement accomplishes the attachment without using an adhesive or bonding agent.

25

Typically the base member is formed in a first injection moulding step and the teeth engaging elements are moulded on to the base member in a second injection moulding step. Preferably, the oral appliance forms a single integral article.

It will be understood that other plastics which are sufficiently strong and rigid and which do not have thermoplastic properties in the appropriate temperature ranges may also be used for the base member.

5 Thus the base member is substantially rigid while the teeth engaging elements are softer than the base member.

Optionally the base member may have breathing apertures defined therein, eg centrally positioned, for permitting breathing therethrough. In a preferred form, 10 there are four elongate slot-like apertures defined in the base member.

Typically the appliance also includes a tongue tag, eg centrally positioned, defined in the inner flange, for correctly positioning the tongue of a user during use.

15

In one preferred embodiment, the oral appliance is adapted for use as an orthodontic appliance. In another preferred embodiment, the appliance is suitable for use as a sports mouth guard.

20 According to another aspect of this invention there is provided a method of making an oral appliance, the method including:

moulding a base member from a plastic material so that the base member defines at least one generally U-shaped channel; and

25 moulding at least one complementary teeth engaging element from a thermoplastic material such that the teeth engaging element is permanently attached to and positioned on said base member in a said channel.

Preferably, the base member is injection moulded from polyurethane,

polypropylene or santoprene and each complementary teeth engaging element is injection moulded from EVA.

Preferably, the base member is moulded with upper and lower channels and two  
5 teeth engaging elements are moulded, one for each of the upper and lower  
channels of the base member.

Thus, the oral appliance may be formed in a two step injection moulding process.  
More specifically, typically the base member is formed in a first die and then  
10 when it has been formed it is removed from the first die and locked into a second  
die where the teeth engaging elements are formed.

The teeth engaging elements surround or enclose the base member to effect  
attachment to the base member.

15 The other features of respectively the base member and teeth engaging elements  
may be as described above with reference to the first aspect of the invention.

An oral appliance in accordance with this invention may manifest itself in a  
20 variety of forms. It will be convenient to hereinafter describe in detail two  
preferred embodiments of the invention with reference to the accompanying  
drawings. However it is to be clearly understood that the specific nature of this  
description does not supersede the generality of the preceding broad description  
of the invention. In the drawings:

25 FIG. 1 is a front three dimensional view of an oral appliance in  
accordance with one embodiment of the invention;  
FIG. 2 is a rear three dimensional view of the oral appliance of FIG. 1;  
FIG. 3 is a part sectional side view of the appliance of FIG. 1;

FIG. 4 is a front three dimensional view of the base member of the appliance of FIG.1; and

FIG. 5 is a rear three dimensional view of the base member of FIG. 4;

FIG. 6 is a front three dimensional view of an appliance in accordance  
5 with a second embodiment of the invention;

FIG. 7 is a rear three dimensional view of the appliance of FIG 6;

FIG. 8 is a part sectional side view of the appliance of FIG. 6;

FIG. 9 is a front three dimensional view of the base member of the  
10 appliance of FIG. 6;

FIG. 10 is a rear three dimensional view of the base member of FIG. 9;  
and

FIG. 11 is a sectional side view of the base member of FIG. 9.

In FIGS. 1 to 5 reference numeral 1 refers generally to an appliance in  
15 accordance with the invention.

The appliance 1 comprises broadly a base member 2 and two teeth engaging  
elements 3 and 4.

20 The base member 2 has a broadly U-shaped configuration sized to complement  
the general U-shape of the jaw of a user when viewed in plan view. The base  
member 2 has a central web 5 and inner and outer flanges 6 and 7 projecting both  
upwardly and downwardly from both the inner and outer edges of the web 5.

25 The web 5 and flanges 6 and 7 collectively define upper and lower channels 10  
and 11 within which respectively the upper and lower teeth engaging elements  
3 and 4 are positioned.

The base member 2 is made of a substantially rigid plastic material having an

appropriate mechanical strength. Polypropylene, polyurethane and santoprene have been found to be very suitable although other plastics may also be used. Polyurethane has been used in the illustrated embodiment.

5 Each of the elements 3, 4 is made of a thermoplastic material which in the illustrated embodiments is EVA. The EVA softens at 90 to 95°C and thus can be softened by placing in boiling water.

Each of the tooth engaging elements 3 and 4 also has a broadly U-shaped 10 configuration when viewed in plan view. This complements the general shape of the base member 2. Each element 3, 4 also has a broadly U-shaped cross sectional configuration with a bottom wall 15 and two side walls 16 and 17. The shape and width of the channels defined in the base member 2 and elements 3 and 4 have been specifically designed so as to enable the appliance to 15 accommodate widely varying jaw widths and thereby be capable of being fitted to a large number of patients. The appliance also includes a notch or cut-out 35 in the upper surface of the outer flange 7. The notch 35 has the important function of permitting inward or outward adjustment of the arms of the U-shaped member without causing distortion of the appliance 10. This assists in fitting a 20 single size appliance to patients with widely different arch sizes.

In the illustrated embodiment, the layer of EVA forming the elements 3, 4 extends continuously across the full surface area of the base member including the outer surface of the flanges 6 and 7 and thus covers more than just the U- 25 shaped channels of the base member 2. The reason for applying the layer of thermoplastic material across the entire surface area of the base member is to mount or attach the EVA layer to the base member which is made of polyurethane, polypropylene or santoprene.

EVA does not bond naturally to the base member when it is moulded onto the base member and thus a way has to be found of securing it to the base member. This is accomplished by mechanically encasing or enclosing the base member within the layer of EVA. The inability of EVA to bond to the plastic base member is a major problem to be overcome in manufacturing these appliances.

5 The appliance has a tongue tag 25 for positioning the tongue in an exact central position. The appliance also has a plurality of holes 30 defined therein that permit mouth breathing. This is essential for playing sports.

10

A further feature of the appliance is that the web of the base member 2 tapers outwardly from the leading edge thereof up to a point thickening the web, and then tapers inwardly after that to the rear end progressively thinning the web. Thus, the web has a cross sectional configuration so as to substantially occupy 15 the space between the teeth of upper and lower jaws of the user. This configuration which is clearly illustrated in the applicant's prior applications may generally be described as an asymmetrical aerofoil shape having a curved surface on the lower side. The web may have a thickness of about 6mm at its thickest point.

20

This supports the jaw of a user and encourages the lower jaw to assume its anatomically correct position relative to the upper jaw. This is believed to cause a relaxation of muscles in the head and the neck. This configuration of the web of the base member opens the "bite" and holds the jaw in a more down and 25 forward position. In this position, the jaw is more resistant to injury. This jaw position is understood to enhance athlete performance. Further, the thickening of the web naturally also strengthens the appliance.

The appliance 1 is made in a two-step injection moulding process. The base

member 2 is injection moulded in a first die from polyurethane. The base member 2 is then switched to a second die having a larger cavity and the layer of EVA, including the teeth engaging members 3, 4, is then moulded onto the base member.

5

The injection moulding process comprises broadly the injection of a viscous resin from a heated cylinder into the die by means of a plunger or injector. The die is cooled by cooling means, e.g. chilled cooling water, causing the resin to cure and harden. The moulded article can then be removed from the die. The injection moulding techniques used to form the appliance would be well known to a person skilled in the art and do not form part of the invention. Therefore, they will not be described in further detail.

In use, the mouth guard may be in one example application be fitted by a dentist 15 in a dental surgery. In other applications, the guard may be fitted by a user. This is done by heating the appliance up to 90°C by soaking it in boiling water. When this occurs the base member remains rigid while the elements 3, 4 soften making them suitable for being customised to the individual tooth and jaw shape of a user. The appliance is then placed in position in the mouth of a user and the 20 elements 3, 4 conform to the user's teeth and jaw and then harden in this position.

In a second embodiment of the invention illustrated in Figs. 5 to 11, the appliance is used for orthodontic treatment. The orthodontic appliance is the 25 same as that illustrated in FIGS. 1 to 5 with the exception that it does not have breathing holes, e.g. for mouth breathing, and the base element 2 is thinner, e.g. having an approximate thickness of 2mm to 4mm, because it does not have the same requirements of mechanical strength as the sports guard. The orthodontic appliance is used for myofunctional training and tooth realignment.

Myofunctional training is a clinical procedure which is designed to correct bad oral habits, e.g. tongue thrusting, mouth breathing, incorrect swallowing and the like.

- 5 In use the appliance is initially fitted by a dentist or orthodontist in a dental surgery. The shape of the elements 3, 4 prior to use corresponds broadly to an ideal positioning or "bite" of a patients teeth. To enable the elements 3, 4 to be tailored to a patients specific teeth, the elements 3, 4 are dipped into boiling water to soften the elements and then inserted into a patients mouth to mould 10 them to the specific contours of a patient's mouth.

The EVA material from which the elements 3, 4 are formed has a memory so that it reverts to its original shape when reheated. It reverts partly to its original shape when heated to 60 to 65°C and fully to its original shape when heated above 15 90°C.

The memory properties of the EVA enable the elements 3, 4 to be used to progressively correct misalignment of a patients teeth. For example at spaced time intervals, the dentist will typically place the appliance into water at a 20 temperature of 60 - 65°C which causes the elements 3, 4 to partly revert to their original shape. The slightly altered shape brought about by this remoulding causes the appliance to apply pressure to the teeth of a user to correct misalignment. This can be done several times until the patients teeth take up the correct position or the ideal "bite" position.

25

When the teeth are in the correct position the appliance can be placed into water at 90 - 95°C which causes it to revert fully to its original position. The appliance can then be used as a retaining device for retaining the teeth in the correct position and also for carrying out myofunctional training.

An advantage of the appliance described above is that it enables industrially manufactured mouth guards to be customised to a user's mouth very easily and simply, e.g. in a dentist's chair or by a user. A further advantage is that the 5 appliance can be applied equally to orthodontic and sports guard applications. A yet further advantage of the appliance is that it effectively attaches the EVA elements to the base member.

The sports mouth guard described above is very effective because it protects both 10 upper and lower teeth and also the jaw joints. The orthodontic appliance provides an inexpensive device for correcting myofunctional and tooth alignment problems.

It will of course be realised that the above has been given only by way of 15 illustrative example of the invention and that all such modifications and variations thereto as would be apparent to persons skilled in the art are deemed to fall within the broad scope and ambit of the invention as is herein set forth.

**CLAIMS:**

1. An oral appliance for placing in a mouth of a user, the appliance including:

5 a base member having a generally U-shaped form corresponding to the outline of a row of teeth of a user, the base member defining at least one channel within which an upper or lower row of teeth of a user can be received; and

10 a teeth engaging element positioned within each channel, the teeth engaging element being made of a thermoplastic material such that it can be conformed or moulded to suit the individual mouth of a user by heating the element to a temperature at which it is plastic and formable.

2. An oral appliance according to claim 1, wherein the base member has inner and outer flanges interconnected by a web which collectively define upper and lower channels within which respectively the upper and lower rows of teeth 15 are received, and wherein there is an upper said teeth engaging element being received within the upper channel and a lower said teeth engaging element being received within the lower channel.

3. An oral appliance according to claim 1 or claim 2, wherein each teeth 20 engaging element has a generally U-shaped transverse profile and which is generally U-shaped as a whole to correspond to the outline of a row of teeth of a user.

4. An oral appliance according to any one of claims 1 to 3, wherein each 25 teeth engaging element is formed of EVA (ethylvinylacetate) which softens at a temperature of 90°C - 95°C and wherein the base is made out of a reasonably rigid plastics material.

5. An oral appliance according to any one of claims 1 to 4, wherein each

teeth engaging element comprises a layer of thermoplastic material positioned on the base member and having a thickness of 1mm – 3mm.

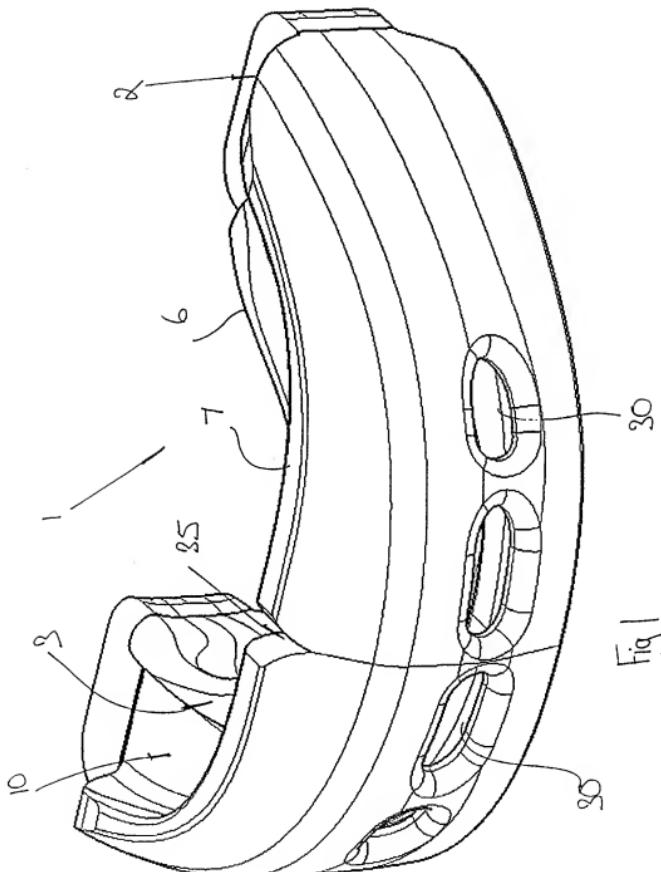
6. An oral appliance according to claim 5, wherein a continuous said layer 5 of thermoplastics material forms both the upper and lower teeth engaging elements, said continuous layer also covering a region of the base member intermediate the upper and lower channels.

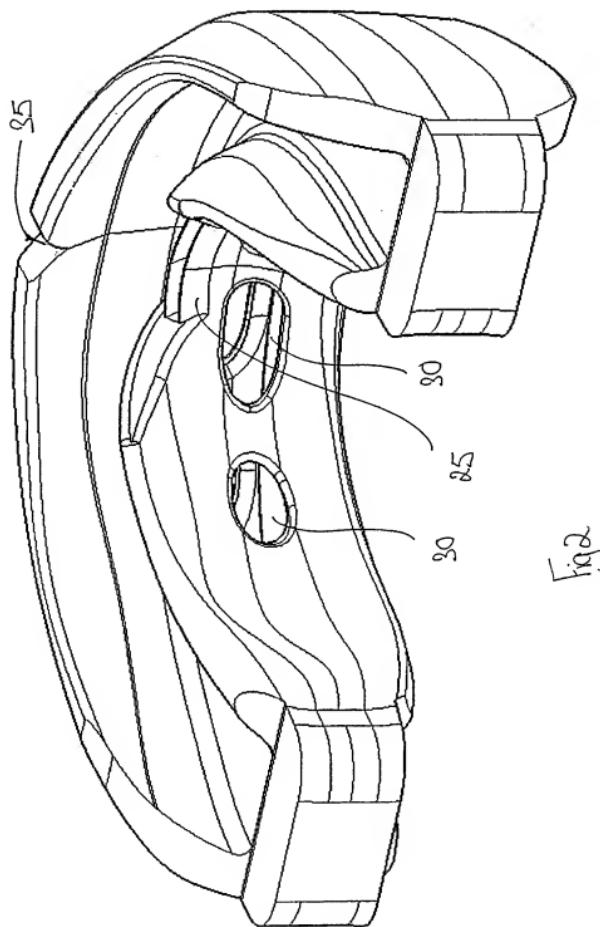
7. An appliance according to claim 6, wherein the continuous said layer of 10 thermoplastic material covers substantially the entire surface area of the base member and wherein the layer is permanently attached to the base member at the time of manufacture.

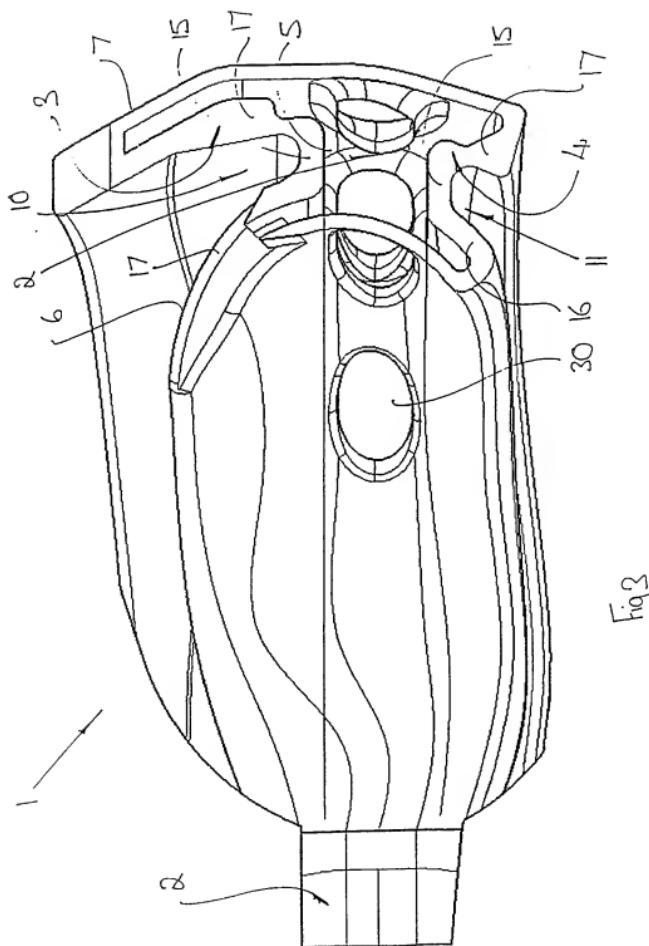
8. An oral appliance according to claim 7, wherein a tongue tag is formed 15 on the inner flange, the tongue tag being substantially centrally positioned for correctly positioning the tongue of a user during use, and wherein the base member has breathing apertures defined therein for permitting a user to breathe therethrough.

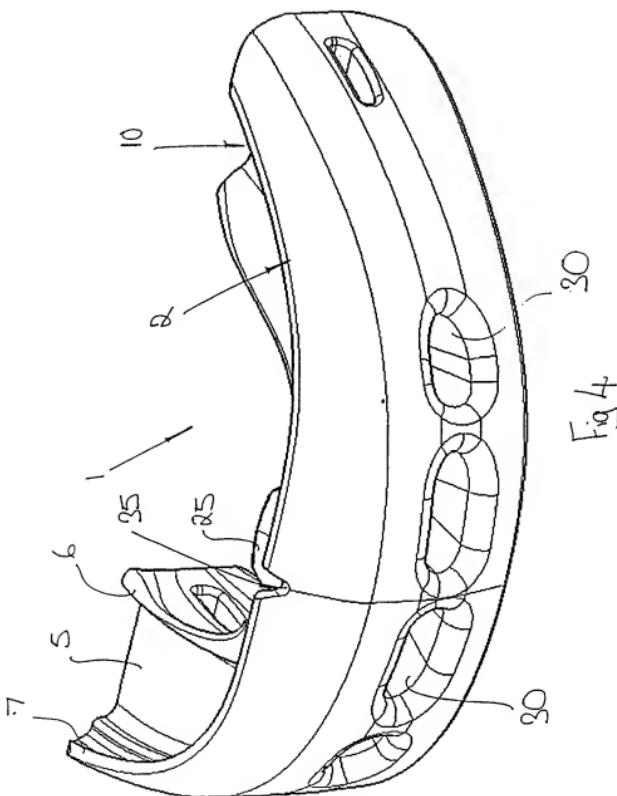
20 9. A method of making an oral appliance, the method including:  
moulding a base member from a plastic material so that the base member defines at least one generally U-shaped channel; and  
moulding at least one complementary teeth engaging element from a thermoplastic material such that the teeth engaging element is permanently 25 attached to and positioned on said base member in a said channel.

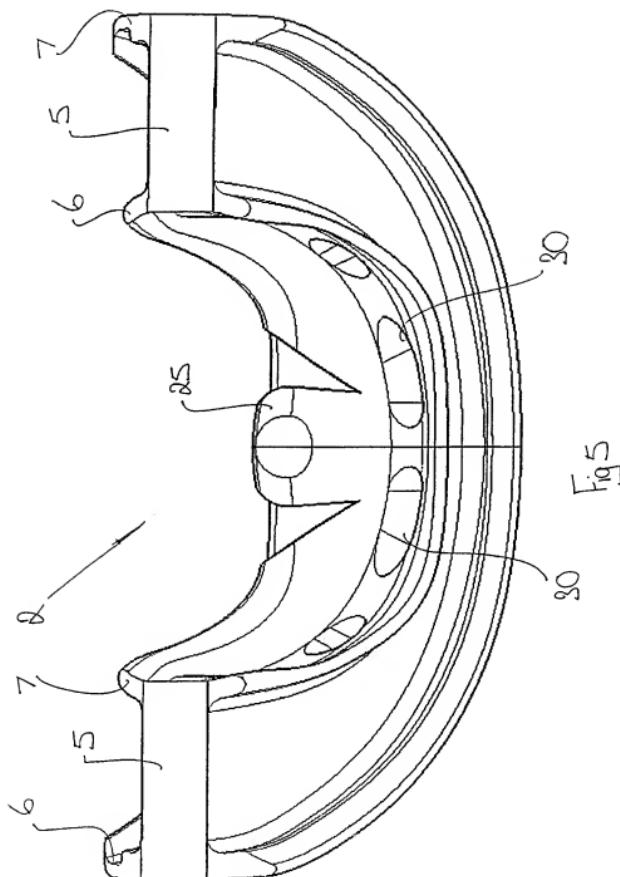
10. A method according to claim 9 wherein the base member is injection moulded from polyurethane, polypropylene or santoprene, and each complementary teeth engaging element is injection moulded from EVA.

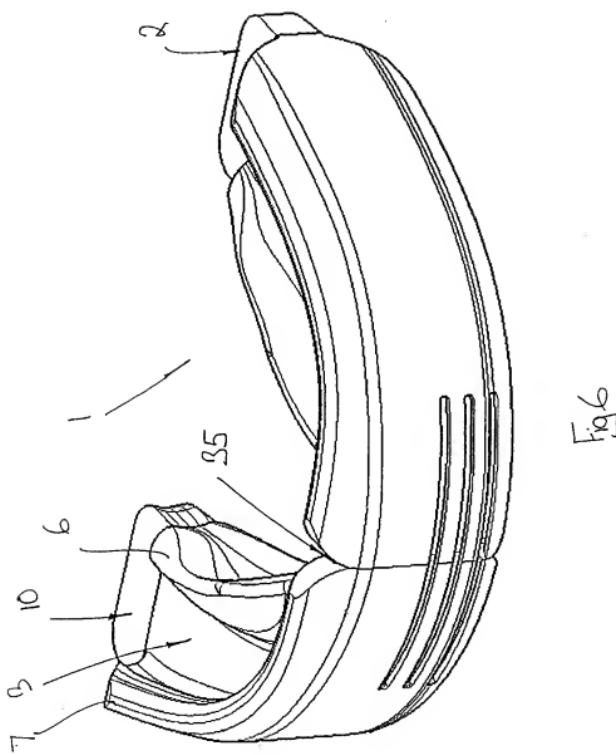


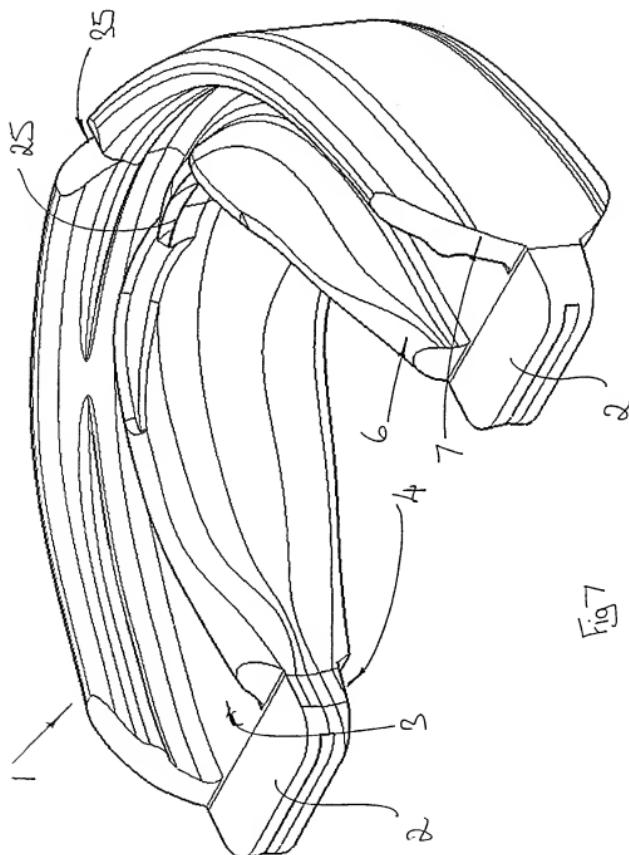


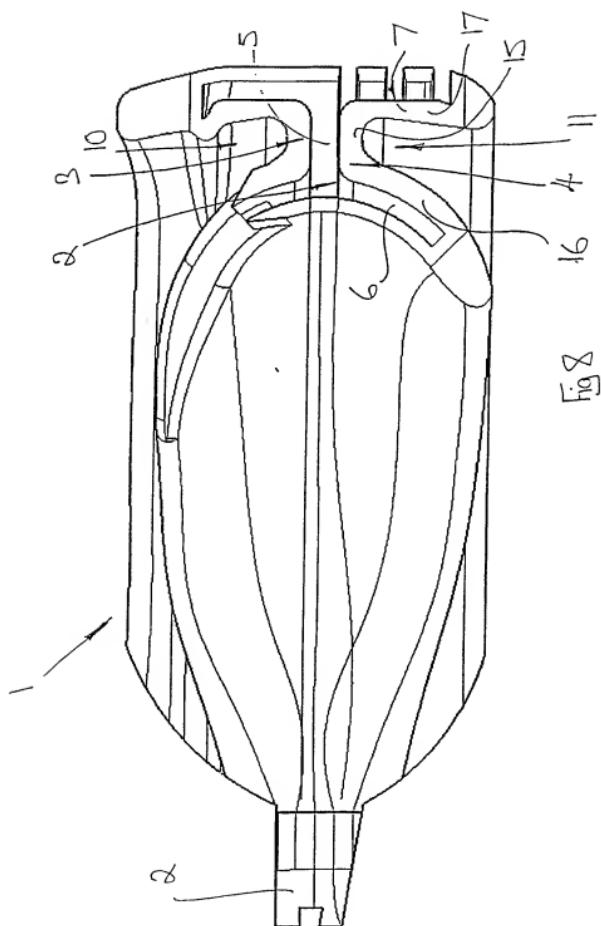


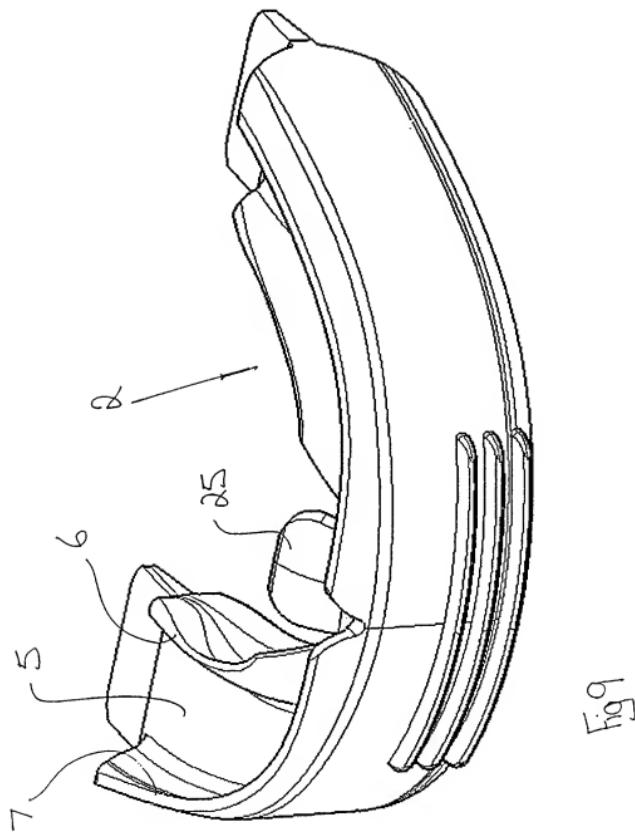


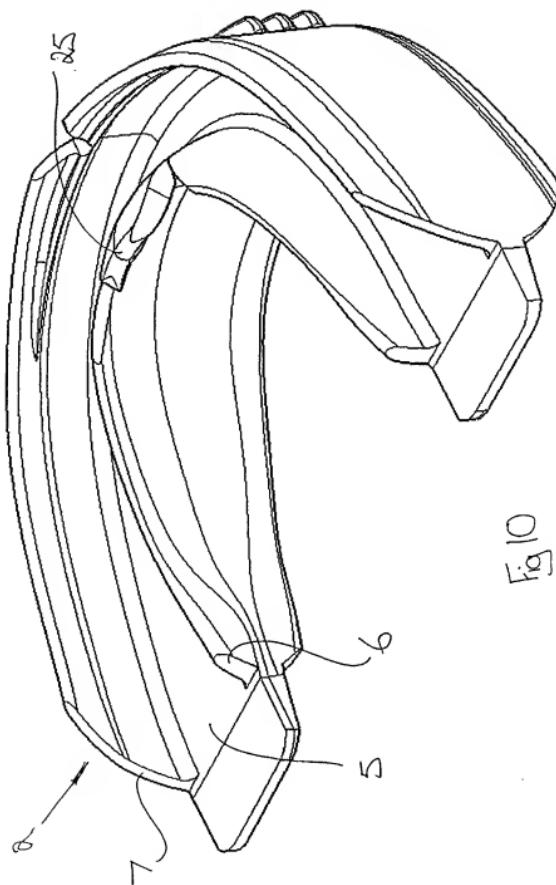


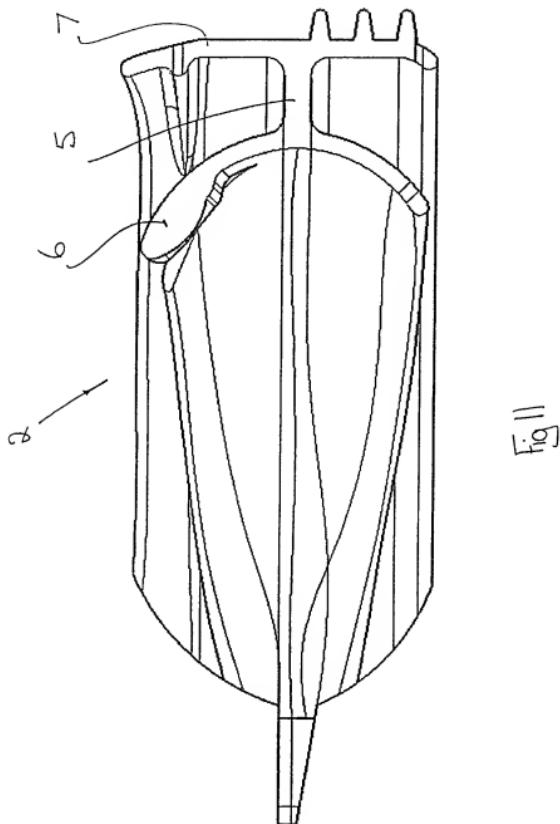












## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/AU 99/00840

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>		
Int Cl <sup>6</sup> : A61C 7/36 A61F 5/01 A63B 71/10		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols)		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) WPAT JAPIO		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CA 2024799 A (ADELL) 25 July 1991 Page 9 line 3 to page 10 line 20 Page 18 line 4 to page 19 line 13	1 - 10
X	US 5092346 A (HAYS et al.) 3 March 1992 Column 4 lines 17 to 38	1-5, 9, 10 6-8
Y	EP 801937 A (MEADE) 22 October 1997 Column 8 lines 17 to 41	1-5, 9, 10 6-8
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C		<input checked="" type="checkbox"/> See patent family annex
<p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&amp;" document member of the same patent family</p>		
Date of the actual completion of the international search 28 October 1999	Date of mailing of the international search report 15 NOV 1999	
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (02) 6285 3929	Authorized officer  <b>DAVID MELHUISH</b> Telephone No.: (02) 6283 2426	

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/AU 99/00840

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 93/08761 A (FARRELL) 13 May 1993 Figure 1	2,8
X	US 5566684 A (WAGNER) 22 October 1996 Column 1 line 62 to column 2 line 6	1, 3-5, 9, 10
Y	FR 2639531 A (BORY) 1 June 1990 Abstract, figure 1	2
Y		6, 7

**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

International application No.  
PCT/AU 99/00840

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report	Patent Family Member			
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END OF ANNEX